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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/862,442	05/23/1997	ANDREW W. SHYJAN	07334/004002	3446

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/03/2002

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/862,442

Applicant(s)
Shyjan

Examiner
Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29, 31-43, and 45-56 is/are pending in the application.
- 4a) Of the above, claim(s) 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29, 31-38, 43, and 45-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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Response to Amendment

1. Claims 43 and 51-56 have been amended. Claims 29, 31-43 and 45-56 are pending. Claims 39-42 remain withdrawn from consideration as no amendment has been filed to cancel these claims. Claims 29, 31-38, 43 and 45-56 are under consideration.

Claim Rejections Maintained

2. The rejection of claims 29, 31-38, 43 and 45-56 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility is maintained. Applicant argues that the cited reference do not teach that the disclosed cDNA would not be translated into a protein. This has been considered but not found persuasive. The reasons of record will be set forth more clearly. The claims are drawn to the polypeptide encoded by the polynucleotides of the fomy030 and fohy030 genes as represented as SEQ ID NO:3, 7 and 9. The specification teaches that the polynucleotides of SEQ ID NO:2, 6, and 8 are downregulated in metastatic cancer cells. The specification does not teach that changes in the levels of the polynucleotide sequences of SEQ ID NO:2, 6 and 8 correlate with changes in the levels of the corresponding encoded proteins, wherein said protein levels would be indicative of a disease state. Although the specification teaches that the fomy030 and fohy030 mRNA is expressed in proliferating non-metastatic tissue in contrast to metastatic cells there is no objective evidence that SEQ ID NO:2, 6 and 8 are translated to SEQ ID NO:3, 7 and 9 at levels which would be commensurate with the levels of mRNA found in the diseased cells. It is recognized in the art that a mRNA level cannot be relied upon as a surrogate for level of the corresponding protein, as a multitude of homeostatic factors control the level of protein expression beyond the level of mRNA transcription. For instance, Shantz and Pegg (Int J of Biochem and Cell Biol., 1999, Vol. 31, pp. 107-122) teach that ornithine decarboxylase is highly regulated in the cell at the level of translation and that translation of ornithine decarboxylase

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mRNA is dependent on the secondary structure of the mRNA and the availability of eIF-4E, which mediates translation initiation. McClean and Hill (Eur J of Cancer, 1993, vol. 29A, pp.2243-2248) teach that p-glycoprotein can be overexpressed in CHO cells following exposure to radiation, without any concomitant overexpression of the p-glycoprotein mRNA. In addition, Fu et al (EMBO Journal, 1996, Vol. 15, pp. 4392-4401) teach that levels of p53 protein expression do not correlate with levels of p53 mRNA levels in blast cells taken from patients with acute myelogenous leukemia, said patients being without mutations in the p53 gene. Thus these references teach that mRNA levels cannot be relied upon to predict levels of the corresponding proteins.

3. The rejection of claims 37, 38, 43 and 45-56 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is maintained. Applicant argues that it is not required that the variant polypeptides must be reduced to practice at the time of filing. However, adequate written description requires that applicant adequately describe a genus of variants by disclosing an adequate number of examples of variant amino acid sequences, or by describing the genus in terms of chemical structure and function. Claims 37 and 38 are drawn to an isolated polypeptide comprising amino acids 1-844 of SEQ ID NO:7 and amino acids 850-1497 of SEQ ID NO:7. There are no examples in the specification of a genus of polypeptides comprising amino acids 1-844 of SEQ ID NO:7 or a genus of polypeptides comprising amino acids 850-1497 of SEQ ID NO:7. Further, claims 37 and 38 do not specify a function limitation for the claimed variants that would assist in defining the genus. Claims 43 and 45-56 are drawn to polypeptides defined by length and hybridization of an encoded sequence. Applicant argues that these claims are limited by the hybridization conditions and the functional limitation that the hybridizing DNA when expressed in a melanoma cell is associated with decreased metastatic potential. However, there are no examples in the specification of a genus of polypeptides

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obtained by the claimed hybridization methods, or a description of necessary chemical features that must be part of the claimed genus.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

December 30, 2001